

Notice of Allowability

Application No.

09/869,169

Examiner

Diana B. Johannsen

Applicant(s)

PAULUSSEN ET AL.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Amendments of 2/23/05 and 8/31/05; the interview of 01/16/06.
2. ☒ The allowed claim(s) is/are 52 and 53.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>part of 0106</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

EXAMINER'S AMENDMENT

1. This action is responsive to the Amendments filed February 23, 2005 and August 31, 2005, and the telephone interview concluding January 16, 2006. Claims 40-51, added by the amendment of February 23, 2005, have now been canceled, and new claims 52-53 have been added and are allowed (see below Examiner's amendment).
2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Hesna J. Pfeiffer on January 16, 2006.

3. In accordance with 37 C.F.R. 1.126, allowed claims 52-53 will be renumbered as claims 1-2, respectively (see MPEP 608.01(j)).

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4. **The application has been amended as follows:**

a) **Cancel claims 40-51.**

b) **Add the following new claims:**

52. A method of identifying the drug metabolizing phenotype of a subject as high or low, wherein said phenotype is associated with cytochrome CYP3A5 expression from variant or wild-type DNA sequences, which method comprises the steps of:

obtaining from the subject a sample comprising genomic DNA;

screening the genomic DNA from said sample for the presence or absence of both variants T₄₇₅G and A₁₄₇G in the transcriptional regulatory region of CYP3A5; and

identifying the subject as having a high drug metabolizing phenotype if both variants are present, or identifying the subject as having a low drug metabolizing phenotype if both variants are absent.

53. The method according to claim 52, wherein during said screening the genomic DNA is amplified using oligonucleotide molecules that hybridize selectively to wild-type or variant DNA sequences, such that generation of amplified DNA indicates whether said variants are present or absent.

Substance of the Interview concluding January 16, 2006.

5. On January 12, 2006 the examiner contacted applicants' representative and proposed modifying new claims 40-41 (rewritten as new claims 52-53) so as to incorporate a step in which subjects are identified as having a particular drug metabolizing phenotype based on the presence or absence of the combination of polymorphisms of the claims, as exemplified in applicants' specification (see, e.g., Example 1, particularly at pages 24-25, and Figure 4A). The examiner noted that this amendment would place these claims in condition for allowance, as the prior art does not teach or suggest the relationship between the polymorphisms of the claims and drug metabolism phenotype (as is taught in applicants' specification). On January 16, 2006, applicants' representative contacted the examiner and agreed to the proposed amendment. Accordingly, new claims 52-53 are now allowed.


Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday and Thursday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Diana B. Johannsen
Primary Examiner
Art Unit 1634